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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/023,096
Filing Date: December 18, 2001
Appellant(s): Marian L. Kruzel

Kurt S. Myers
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 8/7/06 appealing from the Office action mailed 1/31/06.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

This appeal involves claims 1-7.

Claims 8-12 have been canceled.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of claims 1-7 under 35 USC 112, first paragraph, is withdrawn in view of Appellant's arguments.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Chander et al., *Indian dairyman, Vol. 32,* pages 417-418, 1980.

Stiles et al., *Appl. Environ. Microbiol., Vol. 41,* pages 867-872, 1981.

Dickson et al., *Appl. Environ. Microbiol., Vol. 55,* pages 832-836, April, 1989.

Ryser et al. *J. American Dietetic Association, Vol. 89,* pages 948-954, July, 1989.

Webster's Dictionary, 01 March, 1998.

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(9) Grounds of Rejection

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chander et al. ("Chander") in view of Dickson et al. ("Dickson") for reasons of record and the following. Chander teaches that lactoferrin, including bovine, inhibits the growth of a variety of pathogenic and nonpathogenic micro-organisms such as *E. coli*, *Bacillus subtilus*, *Salmonella typhi*, *Vibrio cholerae*, *Shigella dysentriae*, *Klebsiella pneumoniae*, and *Staphylococcus aureus* both *in vitro* and *in vivo* (pages 417-418). Chander does not

disclose that these micro-organisms could contaminate a meat product. Dickson does disclose that *Bacillus subtilus*, *E. coli*, *Staphylococcus aureus*, and *Salmonella typhimurium* do contaminate meat surfaces (abstract and pages 834-835) because of their attachment to lean muscle and fat due to the pathogens' hydrophobicity and surface charges. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lactoferrin to reduce microbial contamination of meat products because Chander teaches that lactoferrin is effective against the same multiple variety of pathogenic and nonpathogenic micro-organisms that Dickson teaches contaminate meat surfaces by their hydrophobicity and surface charges. The economic and public health desire to reduce microbial contamination by using a compound that is already known to be effective against the same microbes that are already known to attach or stick to the surface of meat carcasses (such as the germs that cause *E.coli* or salmonella food poisoning) renders the instant claims *prima facie* obvious. Because lactoferrin is a solid protein in its natural state (i.e. when completely 100% pure and separated from water, lactoferrin is a solid, not a liquid or a gas), the growth medium (page 418) used by Chander to dissolve the lactoferrin in meets the limitations of both a carrier and a nutritionally acceptable carrier as the assay medium is comprised of nutrients acceptable to microorganisms. It would also be *prima facie* obvious to dissolve the lactoferrin in other nutritionally acceptable carriers before applying it to a food product intended for human consumption such as meat. Finally, the amino acid sequence of lactoferrin is identically the same whether it is produced recombinantly or isolated from its natural source, so the product-by-process type of limitation recited in

the instant claims of "recombinantly produced lactoferrin" does not bestow any patentable distinction to the lactoferrin used in the instant invention, absent any evidence to the contrary.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chander et al. ("Chander") in view of Stiles et al. ("Stiles") for reasons of record and the following. The teachings of Chander are as set forth above. Stiles discloses that *E.coli* and *Klebsiella pneumoniae* are serious fecal and nonfecal contaminants from the skin or hides of animals during processing (pages 867-868 and 870-871). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lactoferrin to reduce microbial contamination of meat products because Chander teaches that lactoferrin is effective against both of these food-borne pathogens that Stiles teaches contaminate meat products at the wholesale and retail level. The economic and public health desire to reduce microbial contamination by using a compound that is already known to be effective against the same microbe that is already known to be present in wholesale and retail meats (such as the germs that cause *E.coli* and *Klebsiella* food poisoning) renders the instant claims *prima facie* obvious. Because lactoferrin is a solid protein in its natural state (i.e. when completely 100% pure and separated from water, lactoferrin is a solid, not a liquid or a gas), the growth medium (page 418) used by Chander to dissolve the lactoferrin in meets the limitations of both a carrier and a nutritionally acceptable carrier as the assay medium is comprised of nutrients acceptable to microorganisms. It would also be *prima facie* obvious to dissolve the lactoferrin in other nutritionally acceptable carriers before

applying it to a food product intended for human consumption such as meat. Finally, the amino acid sequence of lactoferrin is identically the same whether it is produced recombinantly or isolated from its natural source, so the product-by-process type of limitation recited in the instant claims of "recombinantly produced lactoferrin" does not bestow any patentable distinction to the lactoferrin used in the instant invention, absent any evidence to the contrary.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chander et al. ("Chander") in view of Ryser et al. ("Ryser") for reasons of record and the following in light of the definitions of "meat" from either Webster's dictionary or *WordNet ® 2.0*. The teachings of Chander are as set forth above. Ryser discloses that gastroenteritis producing food-borne *E.coli* can be enteropathogenic, enterotoxigenic, enteroinvasive, or colohemorragic, and has long been recognized as responsible for numerous cases of infant and travelers' diarrhea (pages 948-949 and 953). Ryser also discloses that *Vibrio cholerae* which causes cholera is present in crab, shrimp, and oysters (pages 948-949 and 952-953), which meet the definition of "meat" as defined either by Webster's dictionary or *WordNet ® 2.0* (the instant specification does not define "meat product," so the Examiner had to rely on extrinsic sources to determine the metes and bounds of the claims). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lactoferrin to reduce microbial contamination of meat products because Chander teaches that lactoferrin is effective against both food-borne pathogens that Ryser teaches cause infant and travelers' diarrhea, cholera, and sometimes death, from the consumption of raw or undercooked

crab, shrimp, oysters, ground beef and ground beef sandwiches. The economic and public health desire to reduce microbial contamination by using a compound that is already known to be effective against both microbes that are already known to be present in raw or undercooked crab, shrimp, oysters, ground beef and ground beef sandwiches (such as the germs that cause *E.coli* food poisoning and cholera) renders the instant claims *prima facie* obvious. Because lactoferrin is a solid protein in its natural state (i.e. when completely 100% pure and separated from water, lactoferrin is a solid, not a liquid or a gas), the growth medium (page 418) used by Chander to dissolve the lactoferrin in meets the limitations of both a carrier and a nutritionally acceptable carrier as the assay medium is comprised of nutrients acceptable to microorganisms. It would also be *prima facie* obvious to dissolve the lactoferrin in other nutritionally acceptable carriers before applying it to a food product intended for human consumption such as meat. Finally, the amino acid sequence of lactoferrin is identically the same whether it is produced recombinantly or isolated from its natural source, so the product-by-process type of limitation recited in the instant claims of "recombinantly produced lactoferrin" does not bestow any patentable distinction to the lactoferrin used in the instant invention, absent any evidence to the contrary.

(10) Response to Argument

Appellant's arguments filed 8/7/06 (the Appeal Brief) have been fully considered but they are only partially persuasive. The Examiner has withdrawn the rejection of claims 1-7 under 35 USC 112, first paragraph, in view of Appellant's arguments.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

In response to Appellant's arguments against the Chander reference making no disclosure as to lactoferrin treating any product, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is the Examiner's opinion that Chander need not make any reference to treating any product because the rejection is based on a combination of Chander and either the Dickson, Stiles, or the Ryser references. The Examiner believes he has set forth non-technical, "common sense" suggestions and/or motivations on how and why the references should be combined for the simple purpose of inhibiting meat spoilage and food poisoning that would render the instant claims *prima facie* obvious to those of ordinary skill in the art, such as food scientists or biochemists concerned with the problem of meat spoilage and food poisoning.

Appellant argues against the Dickson reference by stating that Dickson does not teach that the same lactoferrin-susceptible pathogens disclosed in both Chander and Dickson (thereby providing a common nexus in addition to the motivation already stated

by the Examiner) contaminate meat. This is not found persuasive since the Dickson reference is directed to "why" or the specific mechanism by which certain well-known pathogens, such as *E.coli* and *Salmonella*, found on the surface of meat have the ability to contaminate meat. The concluding sentence of Dickson (page 835) is "we have established that the magnitude of the bacterial cell surface charge is an important factor in attachment to meat," so the Examiner finds Appellant's argument that Dickson does not teach that *E.coli* and *Salmonella* are normal contaminants of meat unconvincing.

Appellant argues against the Stiles reference by noting that "the significance of these organisms in retail meats could not be determined..." (page 8 of the Appeal Brief filed 8/7/05). However, the Examiner notes that this introductory paragraph by Stiles was in reference to the prior art, and that the main thrust of the Stiles reference is to demonstrate the importance of *E.coli* and *Klebsiella pneumoniae* as serious fecal and nonfecal contaminants from the skin or hides of animals during processing (pages 867-868 and 870-871). Appellant's argument that combining the references would "destroy" the "invention" of the Stiles reference in not persuasive because Stiles is relied on for the teaching of what lactoferrin-susceptible pathogens are present on meat naturally, before any treatment, and it provides a common nexus (in addition to the motivation identified by the Examiner) between the Chander and Stiles references because both disclose the same lactoferrin-susceptible pathogens *(E.coli* and *Klebsiella pneumoniae)*. Also, Stiles is a peer-reviewed academic research paper, and unlike a patent, does not disclose an "invention" that can be "destroyed" by the combination of the references.

Similar to his argument against the other references, Appellant argues against the Ryser reference by noting that it does not teach treating any product. The Examiner, while acknowledging Appellant's argument that "there must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination" and "that knowledge can not come from the applicant's invention itself" (*In re Oetiker, 977 F. 2d 1443, 1447 (Fed. Cir. 1992*), would like to point out that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981) (underlining mine). The Examiner has, in fact, followed the precedent set by *In re Oetiker*, by not using the knowledge from applicant's disclosure, but by showing what the combined teachings of the references would have suggested to those of ordinary skill in the art for the reasons already of record. Furthermore, in response to Appellant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA

1971) (underlining mine). In addition, in response to Appellant's argument that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the economic and public health desire to reduce microbial contamination by using a compound that is already known to be effective against microbes that are already known to be present in raw or undercooked crab, shrimp, oysters, ground beef and ground beef sandwiches (such as the germs that cause *E.coli* food poisoning and cholera) renders the instant claims *prima facie* obvious.

Appellant's last argument is that the combination of the references does not provide a reasonable expectation of success. This is unconvincing because Chander discloses that lactoferrin is effective both *in vivo* and *in vitro* (pages 417-418), so one of ordinary skill in the art would reasonably expect lactoferrin would be effective since it retains its desired biological properties both in its natural state (*in vivo*) and in the applied setting of the laboratory (*in vitro*), so this is an affirmative teaching that lactoferrin would be operative in an applied setting, and not just as a natural constituent in milk (i.e., lactoferrin does not lose its effectiveness once isolated or purified from milk, it does not require other milk constituents to be biologically active *per se*, etc.). Given that lactoferrin is normally consumed by animals, including humans, on a daily basis

with no demonstrated ill effect, it is also more likely than not that the simple application of lactoferrin to a meat product would have a reasonable expectation of success of being quite non-toxic and palatable with minimal side effects, unlike many prescribed antibiotics or antiseptics in general use. Lastly, there are no teachings from the prior art of record that diminish any reasonable expectations of success, nor are there any teachings in the instant application that indicate unexpected results.

Therefore, for reasons set forth above, Appellant's arguments have been fully and carefully considered, but are not considered sufficient to rebut the prima facie case of obviousness and it is believed that the rejections should be sustained.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

SG

Stephen Gucker

Art Unit 1649

September 22, 2006

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